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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/080,959 | 02/22/2002 | Patricia Cruz-Perez | 0001-00001 | 1590 |

7590 06/17/2003

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EXAMINER

WILDER, CYNTHIA B

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1637

i/

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
10/080,959

Applicant(s)
CRUZ-PEREZ et al.

Examiner
Cynthia B Wilder

Art Unit
1637



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 31, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above, claim(s) 3-11 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18 is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 1, 2, and 12-17 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some* c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachments

- | | |
|---|---|
| 1 <input checked="" type="checkbox"/> Notice of References Cited: PTO 892 | 4 <input type="checkbox"/> Interview Summary: PTO 413: Paper No. s |
| 2 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review: PTO 946 | 5 <input type="checkbox"/> Notice of Informal Patent Application: PTO 152 |
| 3 <input checked="" type="checkbox"/> Information Sheet for the Applicant: PTO 111: Page 1 of 1 | |

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DETAILED ACTION

Election/Restriction

1. Applicant's election of Group I, claims 1, 2, 12-18 and SEQ ID NOS: 1, 2 and 5 in Paper No. 9 is acknowledged. Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 3-11 and SEQ ID NOS: 3 and 4 have been withdrawn from further consideration as being drawn to a non-elected invention.

Priority

2. Applicant's claim for domestic priority under 35 U.S.C. 119(e) for provisional application 60/280,712, filed March 29, 2001 is acknowledged.

Information Disclosure Statement

3. Information Disclosure statement filed in Paper Nos: 7 and 10 is acknowledged. A signed copy of the form-1449 is attached to this Office Action.

Objections

4. The disclosure and claims are objected to because of the following informalities:

(a) Claims 1, 2 and 12-17 are objected to because the designation for the sequence identifier is

to --SEQ ID NO:--

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(b) The disclosure is objected to at pages 5 and 14 because the designation for the sequence identifier is improper (see MPEP § 2422.03). It is suggested amending the disclosure at pages 5 and 14 by changing "SEQ. ID NO." to --SEQ ID NO:--.

(c) The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code at page 18, paragraph #0041. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Appropriate correction is required.

Closest prior art

5. Claims 1, 2 and 12-18 contain allowable subject matter. Specifically, the prior art does not teach a method for detecting the fungus *Stachybotrys chartarum* utilizing a polymerase chain reaction in the presence of at least one primer having the sequence of SEQ ID NO: 1 or SEQ ID NO: The prior art also does not teach a method of identifying and quantifying the presence of the fungus *Stachybotrys chartarum* in a collected sample wherein DNA standards from a culture of *Stachybotrys chartarum* are obtained and amplified along with a collected sample's DNA using a primer set and probe that is specific for the fungal species *Stachybotrys chartarum* in a polymerase reaction and wherein the amplification plots obtained by the polymerase chain reaction of each of the DNA standards and the collected sample's DNA are compared to determine the presence of and concentration of the fungus *Stachybotrys chartarum* in the collected sample. No motivation was

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6. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. Haugland et al. (WO 01/96612) teach a method for detecting and quantifying specific fungi or bacteria in a sample, e.g., *Stachybotrys chartarum*, the method comprising extracting and recovering DNA from the organism in the sample, subjecting the DNA from the sample to polymerase chain reaction and fluorescent probe analysis in the presence of a primer set and probe that is specific for the organism (see page 5, line 13 to page 6, line 13 and Table 1 at page 20 which disclose the primers and probe specific for *Stachybotrys chartarum*). Haugland et al. also teaches a method of quantifying *Stachybotrys chartarum* using real time detection of PCR products with the TaqMan™ fluoregenic probe system (see pages 40, Example 1). Haugland et al. disclose wherein the amplification products from the target DNA of the *Stachybotrys chartarum* is compared with amplified DNA standards obtained from a culture of a reference target, e.g., *Geotrichum candidum*. Haugland et al. further discloses a primer sequence that is 82.4% identical to the sequence of SEQ ID NO: 1 (see disclosure at page 23, probe AcircP) and a sequence that is 75% identical to the sequence of SEQ ID NO: 2 (see SEQ ID NO: 187). See also Haugland et al. (US Patent 6,387,652 B1) for the same disclosure mention above.

Contact Information

7. Any inquiry concerning this communication or earlier communications from the examiner

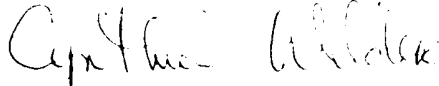
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examiner can normally be reached on Monday through Thursday from 9:30 am to 6:30 pm and on Friday from 9:30 am to 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. The official fax phone number for the Group is (703) 308-4242. The unofficial fax number is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Group's receptionist at (703) 308-0196.

cbw
June 12, 2003



Cynthia B. Wilder, Ph.D.
Patent Examiner
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